APPEAL FROM ASMI

COMPLAINTS PANEL DETERMINATION

SCHERING PLOUGH PTY LTD ("MSD")

V

JOHNSON & JOHNSON PACIFIC PTY LIMITED ("JJP")

ZYRTEC® ADVERTISING

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1 This is an Appeal by JJP against part of a Determination made by the Panel on 8 January 2012. The Complaint was originally made by MSD concerning advertisements by JJP for Zyrtec® antihistamine published in the September 2011 issue of Postscript and in an advertisement for Zyrtec® between June and October 2011 on the internet website "In The Know" (**ITK**).

2 The Panel made determinations in respect of five claims and imposed certain sanctions on JJP. JJP initially sought to appeal against the findings in relation to claims 1, 3 and 4 but subsequently withdrew its appeal in relation to claim 1[1].

Claim 1

3 In the advertisement in Postscript, JJP made the claim that:

> *"Zyrtec® is over twice as effective as Claratyne® at relieving the combined symptoms of hayfever"*

4 The Panel found that this claim was in breach of the ASMI Code (Sections 5.1.3 and 5.2) and the Therapeutic Goods and Advertising Code (**TGAC**) (Sections 4(1)(b), 4(2)(c), 4(4) and 4(5)). In essence, the Panel found that the studies upon which JJP relied to support the Claim were too short to substantiate the Claim, which would reasonably be understood to refer to the usual or average span of a hayfever episode[2]. By withdrawing its appeal in relation to Claim 1, JJP has effectively acknowledged that Claim 1 is misleading.

5 JJP says however, that the studies upon which it relied to support Claim 1 established that the combined effect of the first two doses of Zyrtec® when used as directed is over twice as effective as Claratyne® at relieving the combined symptoms of hayfever[3]. It therefore asserts it should be permitted to make a claim, directed to pharmacy assistants and health care professionals, in the following terms:

> *"The combined effect of the first two doses of Zyrtec® when used as directed, is over twice as effective as Claratyne® at relieving the combined symptoms of hayfever"*

6 The Panel required JJP to give an undertaking in writing to the Executive Director of ASMI to cease publication in any media, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that:

> *"Zyrtec® is over twice as effective as Claratyne®[4]"*

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[1] In its letter of 7 March 2012
[2] Paragraph 16 of the Determination
[3] JJP letter dated 7 March 2012
[4] Paragraph 53(a) of the Determination

JJP asks that I amend the undertaking to expressly note that the decision of the Panel does not preclude JJP from making a claim to the effect of the claim in paragraph 5 above.

7 The Panel also required JJP to publish a retraction in the Postscript which relevantly, required JJP to say:

> *"There is no clinical evidence to support the advertised claim that Zyrtec® is twice as effective as Claratyne® at relieving the combined symptoms of hayfever"*

8 JJP also wishes to have the required retraction amended to make it clear that there is clinical evidence to support a claim that the combined effect of the first two doses of Zyrtec® is twice as effective as Claratyne® at relieving the combined symptoms of hayfever. JJP has put forward a suggested insertion in the retraction which is to be published by it which reads as follows:

> *"However, there is clinical evidence that the combined effect of the first 2 doses of Zyrtec when used as directed, is over twice as effective as Claratyne at relieving the combined symptoms of hayfever*. (*Studies were conducted over 28.5 and 30 hour periods and commenced at the first does. Data on file: Pooled data from Day 2001, Day 1998 and Meltzer 1996 studies)"*[5]

JJP's contentions in relation to Claim 1

9 At the hearing of the Appeal, Counsel for JJP made extensive reference to the studies upon which JJP had originally relied in the advertisement to support Claim 1. He argued that the studies clearly supported a claim that the first two doses of Zyrtec® were at least twice as effective as Claratyne® at relieving the symptoms of hayfever.

MSD submissions on Claim 1

10 MSD submitted that short duration studies were inadequate to support a claim for comparative efficacy. It also adopted the position that if any claim were to be made by JJP in advertisements to the effect that the first two doses of Zyrtec® were more than twice as effective as Claratyne® at relieving symptoms of hayfever, that assertion would have to be examined in the context of the advertisement as a whole to establish whether or not it was misleading.

Determination – Claim 1

11 The statement that "*Zyrtec® is over twice as effective as Claratyne®*" clearly relates, as the Panel found, to the entire period over which hayfever symptoms are

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[5] JJP letter dated 7 March 2012

experienced[6]. The undertaking which JJP has been required to give is that it will not make the claim in the manner in which it is currently expressed, i.e. so that it can be read to mean that the greater effectiveness of Zyrtec® over Claratyne® extends to the full period over which hayfever symptoms are experienced.

12 The essence of JJP's objection to the undertaking which it has been required to give is that the claim is true when limited to the first two doses. Counsel's analysis of the studies relied upon by JJP to support Claim 1[7] would appear to lend some support to that proposition. However, that was not the claim which was made in the advertisement under consideration. It is therefore not necessary for me to make any finding as to the veracity of such a claim for the purpose of this Determination. In any event, it would be necessary to examine any such claim in the context of the advertisement in which it was contained as a whole before one could make a judgment as to whether or not it breached the Code.

13 In my view, there is nothing in the undertaking which the Panel has required JJP to provide which would limit or otherwise obstruct JJP from making a claim which is justified by clinical evidence. Indeed the Panel's Determination makes that clear by requiring that the undertaking to cease publication must be given ... "*until it can be supported by clinical evidence, ...*".[8]

14 In order to meet JJP's objection that the undertaking is too wide, I believe the undertaking ought to be amended to make it clear that the prohibition is to apply to the claim insofar as it represents that it applies to the usual or average span of a hayfever episode.

15 I accordingly amend the undertaking which is required pursuant to paragraph 53(a) of the Panel's Determination to read as follows:

> *"JJP is required to given an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media, including on any website, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that:*
>
> - *Zyrtec® is over twice as effective as Claratyne® in any context in which that representation can be read to apply to the usual or average span of a hayfever episode."*

I deal with the remaining undertakings in paragraph 53(a) of the Panel's Determination below.

16 I also direct that the second paragraph of Retraction No. 1 which formed the attachment to the Panel's Determination, be amended to read as follows:

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[6] Paragraph 16 of the Determination
[7] i.e. Meltzer EO et al 1996; Day JH et al 1998 and Day JH et al 2001
[8] Paragraph 53(a)

"There is no clinical evidence to support the advertised claim that Zyrtec® is twice as effective as Claratyne® at relieving the combined symptoms of hayfever over the usual or average span of a hayfever episode."

17 Having clarified the Retraction, I do not believe it is necessary to include the insertion which has been suggested by JJP. That is a separate claim which JJP may or may not choose to make as an advertisement for its product provided that is supported by clinical evidence and otherwise complies with the Code.

18 The Tribunal directed that Retraction No. 1 is to be published in the next available issue of Postscript. JJP submitted that as the advertisements had not been published since 5 September 2011 it was not appropriate to require Retraction No. 1 to be published in the next available issue of Postscript because any pharmacy assistants who had read the advertisement would now have forgotten it.

19 MSD, on the other hand, submitted that the retraction should be published in August 2012 at the commencement of the next hayfever season.

20 In my view, having regard to the Panel's Determination that Claim 1 is misleading, it is appropriate that JJP be required to publish a corrective statement. However, requiring the publication of that statement to occur at the commencement of the hayfever season would no doubt give MSD a competitive advantage which is not the purpose of the correction. The purpose is to dispel, as far as possible, the past effect of the misleading advertisement. On the other hand, the fact that JJP has exercised its right to appeal which has inevitably caused some delay, should not confer upon it an added advantage of being able to escape the consequences of the finding against it by not having to publish a retraction.

21 In the circumstances, I confirm the Determination made by the Panel that the retraction be published in the next available issue of Postscript.

Claim 3

22 As a third bullet point towards the bottom of the Postscript advertisement which was the subject of the complaint, JJP made the claim that:

"Zyrtec® can be used for extended periods and continues to be effective over time".

23 The Panel found that this claim would be likely to convey to pharmacy assistants acting reasonably, the incorrect representation that Zyrtec® was the only brand which could be used for extended periods and be effective over time.

24 The Panel found that the advertisement raised the issue of why Zyrtec® should be recommended to customers over other available antihistamine products and that the answer to that question was provided in the bullet points towards the bottom of the advertisement. Two of those bullet points refer to competitor products directly.

Accordingly, the third bullet point would be interpreted by a reasonable person to imply a comparative superiority claim notwithstanding that it does not expressly mention a competitor product.[9]

25 The Panel accordingly found that this claim was a Moderate Breach of the Code.[10]

JJP's contentions in relation to Claim 3

26 JJP submitted that in assessing the impact of the claims made in the advertisement, it was important to bear in mind that pharmacy assistants were more familiar than consumers with the performance properties and attributes of OTC medicines. In summary, JJP contends that:

(a) The claim is not expressed to be a comparative claim.

(b) It comes after two other claims which are expressed to be comparative which clearly identify the different points of comparison. Claim 3 does not identify any point of comparison.

(c) The headline namely that "*9/10 people who use Zyrtec® are satisfied*" is not itself a comparative claim.

(d) Reasonable pharmacy assistants know that all second generation antihistamines provide the benefit of being able to be used for extended periods and continue to be effective over time.

(e) The fact that there are competition questions on the last page is not sufficient to make the claim comparative. They are merely intended to test recall, i.e. to ensure that the pharmacy assistant has in fact read all three bullet points.

(f) Even if the question posed by the Panel at paragraph 37 of its Determination, namely that the reader is led to ask the question *"Why recommend Zyrtec® to your customers over other available antihistamine products?",* the answer to the claim contained in the third bullet point is not comparative.

MSD's contentions in relation to Claim 3

27 MSD effectively supports the Panel's finding and points to the placement and proximity of the previous comparative claims to Claim 3.

Determination – Claim 3

28 In my view, the reasonable pharmacy assistant reading the advertisement would conclude that Claim 3 was in fact a comparative claim. The whole point of the

[9] Paragraph 37 of the Determination
[10] Paragraph 39 of the Determination

advertisement is to provide pharmacy assistants with information which would lead them to recommend Zyrtec® over the products of other competitors.

29 The fact that the first two bullet points which precede Claim 3 are express comparative claims would lead the reasonable reader to believe that Claim 3 is effectively a claim that Zyrtec® has the characteristic described in the claim in contrast to the characteristics of other competitors on the market. Accordingly, although the claim itself is not expressed as a competitive claim, in its context it is clearly competitive. The fact that it does not identify a particular competitor would indicate that it applies to the class of competitors as a whole.

30 Although the headline is not comparative, the reader's attention is directed to Claim 3 after reading the first two bullet points which are expressly comparative claims. If Claim 3 had been the first of the bullet points, then the implication may not have arisen.

31 I accept that the reasonable pharmacy assistant may well be aware that competitors' products can also be used over long periods of time. However, it appears to me that the thrust of the advertisement is to displace that knowledge. The question is whether or not the advertisement is likely to be effective in doing so and accordingly in creating a misleading effect upon the reader. In my view, because it follows after two emphatic competitive claims, it is likely to do so.

32 The competition questions on the last page of the advertisement support my view. The competition offers substantial cash prizes which are designed to and would encourage, reasonable pharmacy assistants to read the three questions which are required to be answered in order to win the prizes. The fact that Question 3 which refers to Claim 3 appears again after questions 1 and 2 which are expressly competitive, further tends to reinforce the impression that Claim 3 is intended to be competitive.

33 I concur with the Panel's Determination that Claim 3 is a Moderate Breach of the Code. I also agree with the Panel's requirement that JJP provide an undertaking in relation to Claim 3 as set out in the second bullet point in paragraph 53(a) of the Panel's Determination.

Claim 4

34 This claim concerned the use of the headline in the Postscript advertisement which read *"9/10 people who use Zyrtec® are satisfied"*. It was referenced to *"Jigsaw* Zyrtec® Brand Tracking 2009". The Panel found that this claim was misleading because the word "*satisfied*" would direct the reader to look for what follows in the advertisement as providing an explanation for that term. It would be read in conjunction with the efficacy claims and would accordingly give the impression to the reasonable pharmacy assistant reading the claim that the reason why 9 out of 10 people are satisfied with Zyrtec® is because of its superior efficacy. This was held by the Panel to be misleading because the survey which was used to support

the claim did not explore the reasons given by the people who were interviewed for the purpose of the survey as to why they were satisfied[11].

JJP's contentions

35 JJP says that:

(a) The claim would not be understood by a reasonable pharmacy assistant as relating satisfaction to superior efficacy.

(b) The consumer data held by JJP supports the general claim that 9 out of 10 Zyrtec® users are satisfied.

(c) In the alternative, that the message which the Panel found to be conveyed to pharmacy assistants is supported because the product is in fact effective.

36 At the hearing of the Appeal, Counsel for JJP contended, in addition to the matters raised in JJP's written Appeal, to which I have referred above, the following:

(a) The word "*satisfied*" means "*meeting someone's expectations or desires*". One doesn't need to have a definition of satisfaction in the advertisement.

(b) There are no expressed words to indicate efficacy in the claim. There are a number of other matters that are important to consumers such as price, lack of side effects, packaging, etc.

(c) Further, the bullet point efficacy claims at the bottom of the advertisement are narrow, i.e. Claim 1 compares Zyrtec® with Claratyne® and the second bullet point compares Zyrtec® with Telfast. Accordingly, a reasonable pharmacy assistant would not read Claim 4 as being an implied claim for greater efficacy of Zyrtec®.

MSD's contentions

37 MSD's response was that the references in the three bullet points were clearly references to efficacy and that Claim 4 would be read in that context. It was open to JJP to provide details of why people were satisfied but that information was not given in the advertisement. In its context therefore Claim 4 is a claim for superior efficacy.

Determination – Claim 4

38 In my view, read in the context of the advertisement as a whole, Claim 4 is a claim which implies comparative efficacy. The advertisement is directed at persuading pharmacy assistants to recommend Zyrtec® over its competitors. Because there is no definition in Claim 4 of the word "*satisfied*" the reader is naturally led to consider

[11] Paragraph 44 of the Determination

the other points made in the advertisement to establish why it is that the people who use Zyrtec® are in fact satisfied.

39 The copy which appears immediately below Claim 4, identifies Zyrtec® as "*rapid acting*" and points out that it relieves hayfever and allergy symptoms including sneezing, runny nose, watery/itchy eyes and itchy skin. At that point the reader then knows the use to which Zyrtec® can be put in order to provide satisfaction, i.e. relief from hayfever and allergy symptoms. If the advertisement had stopped there, a reasonable reader might have identified customer satisfaction with the fact that Zyrtec® was "*rapid acting*".

40 However, the bullet points made towards the end of the advertisement and which are the only other points made in the advertisement which could identify why people who use Zyrtec® would be satisfied, are clearly directed at efficacy. Each of the claims made in the three bullet points, claim that Zyrtec® is more effective than its competitors. The first two bullet points being expressed claims for efficacy and the third point being an implied efficacy claim.

41 Dealing then with the arguments put by Counsel to which I have referred above:

(a) The mere fact that the word "*satisfied*" is capable of ordinary definition, does not mean that readers will not look to the remainder of the advertisement to establish the reasons why users of Zyrtec® are satisfied. Those other reasons are comparative efficacy claims.

(b) Whilst there is no expressed claim of efficacy in relation to Claim 4, in the context of the advertisement as a whole it is, in my view, an implied claim as to greater efficacy. If, as Counsel suggested, users of Zyrtec® were satisfied with it because they were happy with the price and its lack of side effects or packaging, that statement could easily have been made. Depending on the way the statement was made, it may well have altered the effect of Claim 4 in the advertisement. However that was not done.

(c) Moreover, as was conceded by JJP in its written submission[12], efficacy is clearly a key factor in consumer satisfaction. The advertisement emphasised Zyrtec®'s claims for efficacy over its competitors by way of the three bullet points. In the result, the reasonable reader must be left with the impression that the reason for customer satisfaction with Zyrtec® is its alleged greater efficacy.

42 JJP has suggested in its Appeal submission that it is erroneous to suggest that a disclaimer cannot have the effect of clarifying a message conveyed by a claim. The Panel did not make any such suggestion. It merely considered the proposed disclaimer in the context of the advertisement which was the subject of the Complaint.

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[12] At page 11

43 The footnote suggested by JJP to the effect that "*user satisfaction may include such factors as efficacy, side effect profile and cost*" would not dispel that impression because the advertisement is clearly aimed at demonstrating that Zyrtec® has greater efficacy than its competitors. The fact that consumers might appreciate such other factors such as the side effect profile and cost, does not dispel the image that they choose Zyrtec® and are satisfied with it because of its greater efficacy. I agree with the Panel's finding in this regard.

44 Finally, the mere fact that the first two bullet point efficacy claims are narrow cannot serve as a basis for suggesting that the Claim 4 would not be read as a comparative efficacy claim. In exactly the same way as Claim 3 would, in my view, be read to be an implied comparative efficacy claim, so would Claim 4. Having read Claim 4, and having read the balance of the advertisement to understand why consumers of Zyrtec® were satisfied, the reasonable pharmacy assistant would, in my view, assess Claim 4 as being a claim that customers were satisfied with Zyrtec® because it was more effective than its competitors. In summary, I agree with the Panel's Determination that Claim 4 is misleading and in breach of section 5.1.3 of the Code and section 4(2)(c) of the TGAC. I agree that the breach is a Moderate Breach.

45 The Panel required JJP to provide an undertaking to cease publication of any representation expressed or implied to the effect that *"customer satisfaction with Zyrtec® is associated with efficacy"*[13]. It did so, presumably upon the basis that it concluded that the study which Zyrtec® provided in support of its claim, did not identify the reasons given by consumers for their satisfaction with the product[14].

46 JJP submitted that it was implicit in the response that if a consumer was satisfied with a product, that consumer would be satisfied that it was effective. This, JJP submitted was so even without confirming market research.

47 It seems to me that it is reasonably self evident that a consumer would not express satisfaction in a product such as Zyrtec® unless that consumer believed it was effective. The vice in Claim 4 is that it portrays to the reasonable reader that the reason why consumers are satisfied with Zyrtec® is that it is more effective than its competitors.

48 In my view therefore, the undertaking ought to be amended to read as follows:

> *"JJP is to give an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media including on any website, until it can be supported by clinical evidence, of any representation, expressed or implied, to the effect that:*
>
> - *Customers are satisfied with Zyrtec® because it is more effective than its competitors."*

[13] Paragraph 53(a) of the Determination
[14] Paragraph 44 of the Determination

Sanctions

49 JJP submits that to the extent that I find that its proposed disclaimers and amendments would dispel the breach, I should review the sanctions imposed by the Panel.

50 In its initial response to MSD's Complaint, JJP offered to clarify Claim 1 by including a reference that clearly identified the studies upon which it relied to support the claim as two day studies[15]. It did not offer to withdraw the claim. Indeed, it contended strongly that the studies supported the claim as made in the advertisement.

51 A disclaimer to the effect suggested by JJP would not, in my view, have assisted to limit the generality of the claim. Nor have I seen any other evidence that JJP offered to modify Claim 1 in any way which would have removed the offending nature of the claim.

52 As JJP points out, the Code does require parties to collaborate in an attempt to resolve complaints informally. However, where a party proposes disclaimers which do not have the desired effect of removing the misleading nature of the claim made, then in the absence of any further evidence to establish that party's willingness to compromise on the wording of the claim, it seems to me that it ought not to be relieved from sanctions if those sanctions are appropriate.

53 The effect of JJP's withdrawal of its Appeal against Claim 1 shows that in fact JJP concedes that it is misleading. In the context of its acknowledged position that the studies upon which it relies go only to the effectiveness of the first two doses, the disclaimer proposed by JJP on appeal[16] does nothing to detract from the generality of Claim 1.

54 In relation to Claim 3, JJP did not put forward any suggested disclaimers which might have alleviated the effect of the generality of the claim.

55 In relation to Claim 4, as I have noted above, the proposed disclaimer would not, in my view, have had the effect of mitigating the generality of the claim.

56 In summary therefore, where JJP has proposed disclaimers, those disclaimers would not have been effective to dispel the misleading effects of the claims made. In that context, it is not, in my view, appropriate to reduce the sanctions imposed by the Panel in its Determination.

57 At paragraph 50 of its Determination, the Panel stated that it did not know whether publication of the advertisement in any medium had ceased altogether[17]. JJP points out that in its formal response to MSD's Complaint, it advised the Panel that

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[15] Paragraph 3.4 page 8 of JJP's letter of 24 November 2011
[16] Paragraph 8 above
[17] At page 8 of the Determination (first bullet point)

the advertisements in question had not been published since 5 September 2011. This included the Postscript advertisement. JJP requested the Panel to correct the statement in its final Determination which it did not. I assume that when the Panel said that it did not know whether publication of that advertisement "*in any medium has ceased altogether*" it was referring not only to Postscript but any other form of advertisement in which the offending claims are made. It was for that reason that this statement was not removed from the Panel's determination.

58 JJP did not dispute the other findings of the Panel, namely that it had previously been found to breach the Code[18]. JJP did not suggest that if I upheld the Panel's Determination I should disagree with the Panel's finding that this is a case of Repeat Breach as defined in section 9.1 of the Code.

59 The nature of the breaches I have found is such that they would impact on the perceptions of consumers regarding the product and having regard to the fact that health care professionals must be treated as consumers, the breaches are Moderate Breaches within the meaning of section 9.1 of the Code.

60 I therefore agree with the penalty imposed by the Panel at paragraph 53(c).

61 I accordingly require JJP:

(a) To give an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media, including on any website, until it can be supported by clinical evidence, of any representation, expressed or implied, to the effect that:

- *Zyrtec® is over twice as effective as Claratyne® in any context in which that representation can be read to apply to the usual or average span of a hayfever episode*
- *Only Zyrtec® can be used for extended periods and continues/will continue to be effective over time*
- *Customers are satisfied with Zyrtec® because it is more effective than its competitors*

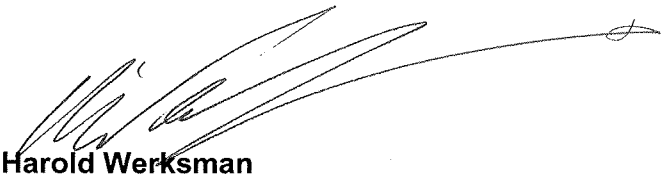
(b) To publish retraction statements in the terms and in accordance with the directions contained in the Attachment to this Determination.

(c) To pay a fine of $40,000 for the Repeat Breaches (other than in relation to Claim 5) found by the Panel, which are to be treated as a single Repeat Breach.

62 I have not been asked to nor do I interfere with the Panel's Determination in respect of the claims which are not the subject of appeal and in particular I assume that JJP

[18] Last bullet point page 8 of the Determination

has published Retraction No. 2 as required by paragraph 53(b) of the Panel's Determination.



Harold Werksman
Arbiter
26 March 2012

Attachment

Retraction

"RETRACTION - ZYRTEC® effectiveness

Recent advertising by Johnson & Johnson Pacific has been found in breach of the ASMI Code of Practice.

There is no clinical evidence to support the advertised claim that Zyrtec® is twice as effective as Claratyne® at relieving the combined symptoms of hayfever over the usual or average span of a hayfever episode.

Accordingly the advertised claim was misleading and not based on substantiated facts.

Johnson & Johnson Pacific has been ordered by ASMI Complaints Panel to publish this retraction"

Directions for Retraction

1. The retraction is to be published in the next available issue of Postscript.
2. The retraction statement to be full page, within the first 6 pages of the publication.
3. The JJP logo or name to appear prominently.
4. No other material emanating from JJP to appear on the same page nor on an adjoining page.
5. Font size of heading to be a minimum of 36 point in bold.
6. Font size of body copy to be a minimum of 28 point in bold.
7. All type to be black.